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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,934	07/24/2003	Kenneth David Reginald Setchell	CHM-013M1	9470

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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT	PAPER NUMBER
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1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/625,934	Applicant(s) SETCHELL ET AL.	
	Examiner Susannah Chung	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-19 and 27-49 is/are pending in the application.
- 4a) Of the above claim(s) 27-43 and 46-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-19, and 44-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-2, 4-19, and 27-49 are pending in the instant application. Claims 3 and 20-26 are canceled.

Response to Non-Final Office Action

Acknowledgment is made of applicant's response and amendment of the claims filed on 2/27/2007.

Scope

Applicant requests reinstatement of Claims 46-49 as being drawn to the elected subject matter. Claims 46-49 are drawn to a food supplement, while claim 1 is directed to a composition. The scope of the claims are different and restriction is proper. Therefore, claims 46-49 will not be rejoined with the elected subject matter.

103 Rejection - Gorbach

Claims 1-2, 4-5, 12-17, 19, 44 and 45 were rejected as obvious over Gorbach et al. (US Pat. No. 6,060,070 ('070 Patent)). Applicants traverse because (1) Gorbach can not be relied upon to show that equol is a racemate, (2) Gorbach is not enabling for the use of "equol" in commercial products. Examiner respectfully disagrees.

First, Gorbach does not need to expressly state that that equol is a racemate. It is well known in the art that if stereochemistry is not discussed then it is presumed to be a racemate. Racemates are products of reagents and reaction conditions that are all symmetrical. (See March, 4th Edition, Advanced Organic Chemistry, page 106.) Racemates are the default products because they are faster, easier, and cheaper to produce than using reagents and reaction

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conditions with chiral centers. Although Gorbach does not state the type of equol used, one skilled in the art would assume that a racemic mixture was used in the products.

Second, Gorbach is enabling for the use of “equol” in commercial products. MPEP §2106(V)(2) provides that an “enabling disclosure” is sufficient if an applicant’s specification enables a person skilled in the art to make and use the claimed invention without undue experimentation. The fact that experimentation is complex, however, will not make it undue if a person of skill in the art typically engages in such complex experimentation. In the instant case, Applicants point out that Gorbach does not provide the commercial source of equol. Gorbach discloses that isoflavonoids are naturally occurring substances. (See ‘070 Patent, Column 2, line 15.) If it is within the ability of one skilled in the art to isolate the equol, either commercially or in the lab, then the disclosure is enabling. The claims of Gorbach clearly state that equol is used in compositions, such as confectionary bars, cereals, biscuits, beverages, pills, capsules, tablets, powders, syrups, etc... (See ‘070 Patent, Columns 3 and 4.) The claims are clear and one skilled in the art would know that it was the intent of the inventor to use equol in food products.

103 Rejection – Gorbach in view of Miller

Claims 18, 44, 45 were further rejected as obvious over Gorbach et al. (US Pat. No. 6,060,070 (‘070 Patent)) in view of Miller et al. (US Pat. No. 6,159,959 (‘959 Patent)). Applicants traverse because (1) Gorbach can not be relied upon to show that equol is a racemate, (2) Gorbach is not enabling for the use of “equol” in commercial products, and (3) Neither Gorbach nor Miller disclose or suggest C-4’ or C-7 conjugates of equol as provided in Claims 18, 44, and 45. Examiner respectfully disagrees.

For reasons (1) and (2) see above.

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The third reason for traversal is that the C-4' or C-7 conjugates of equol are not taught in

Miller. Miller claim 18 reads:

18. A pharmaceutical composition of claim 17 wherein the one or more estrogens are selected from equilin,

equilenin, ethinyl estradiol, 17 β -estradiol, dihydroequilenin, 17 β -dihydroequilenin, menstranol, conjugated estrogens, sulfate esters of estrone, Sodium estrone sulfate, Sodium equilin sulfate, Sodium 17alpha-dihydroequilin sulfate, Sodium 17alpha-estradiol sulfate, Sodium Delta8,9-dehydroestrone sulfate, Sodium equilenin sulfate, Sodium 17beta-dihydroequilin sulfate, Sodium 17alpha-dihydroequilenin sulfate, Sodium 17beta-estradiol sulfate, Sodium 17beta-dihydroequilenin sulfate, Estrone 3-sodium sulfate, Equilin 3-sodium sulfate, 17alpha-Dihydroequilin 3-sodium sulfate, 3beta-Hydroxy-estra-5(10), 7-dien-17-one 3-sodium sulfate, 5alpha-Pregnan-3beta-20R-diol 20-sodium sulfate, 5alpha-Pregnan-3beta, 16alpha-diol, 20-one 3-sodium sulfate, delta(8,9)-Dehydroestrone 3-sodium sulfate, Estra-3beta, 17alpha-diol 3-sodium sulfate, 3beta-Hydroxy-estr-5(10)-en, 17-one 3-sodium sulfate or 5alpha-Pregnan-3beta, 16alpha, 20R-triol 3-sodium sulfate, equol or enterolactone; or a pharmaceutically acceptable salt or ester thereof.

Applicant asserts that "20R-triol 3-sodium sulfate" in the second to last row of Claim 18 is not an estrogen by itself, but is meant to be read along with "5-alpha-Pregnan-3beta, 16alpha, 20R-triol 3-sodium sulfate." This may be the case, but the '959 Patent still teaches the estrogen, albeit a more specific one than Applicants, but the same type of estrogen. One skilled in the art knowing of the specific types of estrogens that could be combined with equol would know that more generic types of estrogens could be combined as well.

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Applicants argue that the compositions in Gorbach and Miller are different and do not suggest the instantly claimed compositions, but Applicants do not point to data or declaration showing any difference in the activity between the prior art compositions and the instant compositions. Absent a showing of unexpected results, one skilled in the art would be able to use the teachings from Gorbach and Miller to use equal in compositions. Therefore, Claims 1-2, 4-5, 12-19, 44 and 45 are finally rejected as being obvious over Gorbach and Miller.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

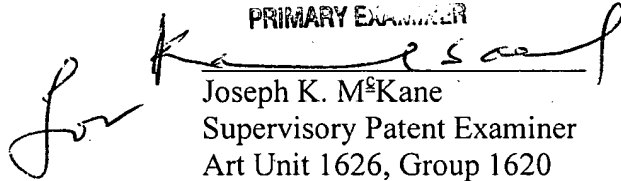
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Chung
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Date: 16 March 2007